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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and Declaration Regarding Emergency Use of in vitro Diagnostics for Detection of Middle East respiratory syndrome coronavirus (MERS-CoV)

AGENCY: Department of Health and Human Services, Office of the Secretary

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, 21 U.S.C. § 360bbb-

3. On May 29, 2013, the Secretary determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Middle East respiratory syndrome coronavirus (MERS-CoV).

On the basis of this determination, she also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Middle East respiratory syndrome coronavirus (MERS-CoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration are effective May 29, 2013.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing 1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or 2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: 1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear ("CBRN") agent or agents; 2) the identification of a material threat by the Secretary of

Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act¹ sufficient to affect national security or the health and security of United States citizens living abroad; 3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent or agents; or 4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.²

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the FDA, HHS, issue an EUA for in vitro diagnostics for detection of Middle East respiratory syndrome coronavirus (MERS-CoV) to allow the Department to take preparedness measures based on information currently available about the Middle East respiratory syndrome coronavirus (MERS-CoV). The determination of a significant potential for a public health emergency, and the declaration that circumstances exist justifying emergency use of in vitro diagnostics for detection

¹ 42 U.S.C. § 247d-6b

² As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. § 247d to support a determination or declaration made under section 564 of the FD&C Act.

of Middle East respiratory syndrome coronavirus (MERS-CoV) by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for certain in vitro diagnostics for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On May 29, 2013, pursuant to section 564 of the FD&C Act, I determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Middle East respiratory syndrome coronavirus (MERS-CoV).

III. Declaration of the Secretary of Health and Human Services

Also on May 29, 2013, on the basis of my determination of a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Middle East respiratory syndrome coronavirus (MERS-CoV), I declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Middle East respiratory syndrome coronavirus (MERS-CoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the Federal Register as required under section 564 of the FD&C Act.

May 29, 2013

Dated

Kathleen Sebelius

Secretary

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